observational study. It was conducted from September 2011 to December 2012 and included a total of 1,109 patients who were scheduled for lumbar spinal surgery from 44 spinal centers (both orthopaedic surgery and neurosurgeons). Patients were diagnosed of having NP if the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale criteria were ≥12 points. The patients were investigated to assess their pain severity using pain numeric rating scale (NRS) and quality of life using EuroQol (EQ)-5D at baseline, after 1 week and 3 months of the surgery. **RESULTS:** Among 1,109 patents, at baseline, NP was identified in 404 (36%) patients. After 1 week and 3 months of the surgery, NP was found in 8.6% and 4.0% patients respectively. Among the 705 patients without NP preoperatively, the prevalence of de novo NP occurred in the 1 week and 3 months of post-surgery was 3.1% and 2.3% respectively. At baseline, NP patients showed lower QoL compared with non-NP patients (0.49 vs 0.53 p<.001). However, NP patients improved more their QoL compared to non-NP patients after 3 months (0.86 vs 0.84 p=.029). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved after 1 week and 3 months of the surgery. **CONCLUSIONS:** In Korea, NP patients were suffered from severe pain and lower QoL than non-NP patients. De novo NP caused severe pain which may not easily be handled. Those study findings highlight that timely diagnosis and management of NP are required in patients with lumbar spine surgery.

PSY82

THE PAIN ASSESSMENT FOR LOWER BACK SYMPTOMS (PAL-S): REFINEMENT OF A NEW PRO INSTRUMENT THROUGH A MIXED METHODS APPROACH

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OBJECTIVES: The Pain Assessment for Lower Back Symptoms (PAL-S) is a Patient Reported Outcome (PRO) instrument being developed to assess the key symptoms of chronic low back pain (cLBP). Qualitative development included both concept elicitation and cognitive interviews. As part of the ongoing development of the instrument, we further evaluated and refined the PAL-S using a mixed methods approach. **METHODS:** Adults self-reporting a clinical diagnosis of cLBP were recruited from an existing US-based commercial survey panel to participate in a pilot quantitative study. Qualifying participants completed a web-based survey consisting of the 14-item PAL-S and items assessing clinical, treatment, and demographic characteristics. Study data was analyzed to assess item- and scale-level performance of the PAL-S using Rasch Measurement Theory analyses. Following analysis and modification, two waves of cognitive interviews were conducted to evaluate respondent understanding of the revised PAL-S. **RESULTS:** The dataset included 598 respondents (mean age: 55.5±12.6; 67.9% female; 88.0% white; and 54.0% married) who had cLBP for mean of 15.2±11.5 years. The Rasch analyses item threshold maps showed only two items having ordered thresholds, suggesting that respondents experienced increased difficulty distinguishing between options at the lower levels of the 0-10 scale. Simulations collapsing the responses to a best-fit 4-point response scale resulted in improved ordering of thresholds, suggesting a more optimal response option structure. Based on these findings, the numeric response scale of the PAL-S items was replaced with a 4-point verbal rating scale incorporating response choices such as *not at all*, *slight*, *moderate*, and *severe*. Findings from eight cognitive interviews confirmed patient comprehension and relevance of the revised instrument. **CONCLUSIONS:** The mixed-methods approach proved valuable to the ongoing development of the PAL-S, as Rasch analyses identified a need for refinement of the response scale. The measurement properties of the revised PAL-S will be evaluated in additional web-based and clinic-based quantitative studies.

PSY83

IMPACTS OF LOWER BACK PAIN: REFINEMENT OF THE PAIN ASSESSMENT FOR LOWER BACK-IMPACTS QUESTIONNAIRE (PAL-I) USING A MIXED METHODS APPROACH

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OBJECTIVES: The Pain Assessment for Lower Back-Impacts (PAL-I) is a patient-reported outcome (PRO) instrument being developed to assess key impacts, e.g. walking, sitting, standing, etc. associated with chronic low back pain (cLBP). Following a mixed methods approach, the PAL-I development included qualitative work (both concept elicitation and cognitive interviews) and now a quantitative "pilot study" evaluation for further content validity. **METHODS:** Adults self-reporting a clinical diagnosis of cLBP were recruited from a US-based commercial survey panel. Qualifying participants completed a web-based survey consisting of the 13-item PAL-I and items assessing clinical, treatment, and demographic characteristics. Study data was analyzed to assess item- and scale-level performance of the PAL-I using Rasch Measurement Theory analyses. Following analysis and modification, cognitive interviews were conducted to evaluate patient understanding of the revised PAL-I. **RESULTS:** The 598 subjects in the pilot study reported having cLBP (mean of 6.1 on 11-point numerical rating scale, 0=no pain). Subjects experienced cLBP for 0.3 to 66 years (mean 15.2, SD 11.5), were 55.5 years old (SD 12.6), 67.9% female, 88.0% white and 54.0% married. The Rasch item threshold map showed only 2 items having an ordered threshold identifying problems with the response categories. Category probability curves indicated subjects had "difficulty" endorsing items specifically in relation to the extreme options. Based on these findings, four items were removed and the response options were modified for the remaining items (from 6-point scale 4-point: *Not at all limited*, *Limited a little*, *Limited a lot*, *Did not do*). Comprehension of the revised instrument was evaluated and confirmed during eight individual cognitive interviews. **CONCLUSIONS:** The mixed-methods approach provides valuable support in the development of a fit-for-purpose instrument assessing impacts of cLBP. Upon testing this revised PAL-I in a second pilot quantitative study, the final measure will undergo formal validation including sensitivity to change.

PSY84

PRO CLAIMS IN ORPHAN MEDICINES APPROVED BY THE EUROPEAN MEDICINES AGENCY (EMA) FOR THE TREATMENT OF LYMPHOPROLIFERATIVE DISORDERS

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OBJECTIVES: 1) To identify orphan medicines indicated for lymphoproliferative disorders approved by the European Medicines Agency (EMA); (2) To identify medicines for which a PRO evaluation was performed; (3) To list those with a PRO labeling claim, and (4) To identify reasons for not granting a PRO claim. **METHODS:** The search was performed on the EMA website (06/21/2014). The products were browsed by type (i. e., orphan medicines). Products refused and withdrawn were excluded. The PROLabels database was searched for each product retrieved to identify any PRO claim in the label. Summary of Product characteristics (SMPc) and CHMP Assessment Reports (AR) were retrieved for each product and analyzed to find out about PRO evaluation reported in the AR and not reported in the label. **RESULTS:** Thirteen orphan medicines indicated in lymphoproliferative disorders were identified, representing three main indications: lymphomas (Hodgkin, systemic anaplastic large cell, T-cell lymphoblastic, mantle-cell), leukemias (chronic lymphocytic, hairy cell, acute lymphoblastic) and multiple myeloma. Only one product had a PRO claim: ofatumumab (resolution of constitutional symptoms). The label of another product (brentuximab vedotin) indicated "resolution of B symptoms." However, there was no mention in the AR on how the symptoms were collected (patient or clinician). For one product (pomalidomide), a HRQL evaluation was mentioned in the AR, but not reported in the label. However, there was no information about this evaluation in the AR and the reader is left to wonder about the HRQL results and the reasons for not including them in the label. **CONCLUSIONS:** The percentage of PRO claims in orphan medicines (7.7%) is inferior to the percentage of PRO claims in all EMA products (26%). This is remarkably low considering the profound effect of lymphoproliferative disorders on patients' life. Efforts should be made to improve the reporting of PRO data in the CHMP Assessment Reports.

PSY85

PSYCHOMETRIC VALIDATION OF THE NEWLY DEVELOPED PHENYLKETONURIA–QUALITY OF LIFE (PKU-QOL) QUESTIONNAIRES ASSESSING THE IMPACT OF PHENYLKETONURIA AND ITS TREATMENT ON PATIENTS' QUALITY OF LIFE

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OBJECTIVES: Phenylketonuria (PKU) is a rare genetic disorder impacting phenylalanine (Phe) metabolism. Treatment involves a lifelong Phe restricted diet that is strict and socially demanding. Even when treated early and well, mild cognitive abnormalities have been seen. PKU can affect quality of life in individuals and their families. The phenylketonuria–quality of life (PKU-QOL) questionnaires are the first PKU-specific QOL questionnaires ever developed. The study aimed to perform the psychometric validation of these questionnaires. **METHODS:** An observational study was conducted in France, Germany, Italy, The Netherlands, Spain, Turkey and the UK to finalize and validate PKU-QoL questionnaires in individuals with treated PKU aged 9–11, 12–17 and ≥18 years, and in parents of individuals <18 years. Questionnaires were assessed for reliability (internal consistency, test–retest), concurrent validity (using three generic questionnaires adapted to the respondent: PedsQOL, SF-36 for adults and CHQ-PF28) and clinical validity (using PKU severity and overall assessment of patient health status). **RESULTS:** In total, 559 participants (306 individuals, ages 9–45 years; 253 parents, ages 24–66 years) were included in the analysis. Return rate and quality of completion of the questionnaires were good, indicating good acceptability. Scores were defined to assess all relevant aspects of experiences: PKU symptoms, impact of PKU, dietary protein restriction and supplementation. Reliability and validity were satisfactory overall for the adolescent, adult and parent PKU-QoL questionnaires, and slightly weaker but acceptable for the child version. **CONCLUSIONS:** The four PKU-QOL questionnaires are valid and reliable instruments for assessing the specific quality of life aspects that are affected in individuals with PKU of different age groups (children, adolescents and adults) and their parents, and are available in seven languages. They are very promising tools for focused evaluation of PKU impact on individuals and parents in different countries, and for monitoring the efficacy of therapeutic strategies.

PSY86

EVALUATING RELATIONSHIP BETWEEN WHITE BLOOD CELLS AND PLATELETS DURING RECOVERY PHASE IN DENGUE HEMORRHAGIC FEVER CASES IN PUNJAB, PAKISTAN: A RETROSPECTIVE STUDY

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OBJECTIVES: Dengue infection is a major cause of disease in tropical areas with an estimated 50 million infections occurring each year and more than 2.5 billion people being at risk of infections. The main objective of this study was to investigate relation between white blood cells and platelets during recovery phase in dengue hemorrhagic fever. **METHODS:** A retrospective multi-center study was conducted on 1000 seropositive cases of dengue fever. **RESULTS:** More prevalence has been observed in male 880 (88%) as compared to female 120 (12%). A rapid fall in white blood cells count (WBC) was observed in initial CBC reports at start of disease then

in platelet count. During recovery phase WBC count increased first followed by platelets count production after 3-4 days. Among 1000 confirmed dengue fever patients 812 were considered dengue hemorrhagic fever cases on the basis of clinical finding. In most of these cases (n=783; 96.47%), directly proportional relation was observed between WBC and platelets count. **CONCLUSIONS:** It is wrongly perceived in community that dengue virus infection is still progressing when platelets count is below normal even the white blood cells counts is getting better during recovery phase. White blood cells production during recovery phase is a good indicator about recovery of disease rather than focused on platelets counts production.

PSY87

PHYSICIANS' AND PATIENTS' PREFERENCES OVER THE ATTRIBUTES OF BIOLOGICAL AGENTS USED IN THE TREATMENT OF RHEUMATIC DISEASES IN SPAIN: A CONJOINT ANALYSIS

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OBJECTIVES: To define the importance values assigned to the attributes of biological agents (BA) by Spanish rheumatologists and patients with rheumatic diseases: rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PA). **METHODS:** Observational, cross-sectional design based on conjoint analysis. RA, AS and PA patients diagnosed at least 2 years prior and currently or previously (≤1 year ago) receiving BA for a minimum of 1 year were consecutively recruited. Rheumatologists with at least 3 year experience on BAs participated. A literature review and 4 focus groups were undertaken to identify attributes and levels. Scenarios were selected using orthogonal design. Participants ranked 8 scenarios from 1 (most preferred) to 8 (least preferred). Relative importance (RI) of attributes was calculated. Multivariate regression analysis was performed for each attribute. **RESULTS:** 488 patients [male=50.9%; mean (SD) age=50.6 (12.06) years; RA=33.8%, AS=32.4%, PA=33.8%; mean time from diagnosis=12.6 (8.2) years] and 136 rheumatologists [male=50.4%; mean age=46.4 (9.1) years; mean time of practice=16.7 (8.8) years] took part. Most important attributes selected by patients and physicians, respectively, were: 'Pain relief and improvement of the functional capacity' (RI=49.1% and 48.9%); 'Risk of adverse events' (RI=31.8% and 31.5%), 'Administration method' (RI=10.2% and 11.4%) and 'Time to perceive the need for a new dose' (RI=9.0% and 8.2%). The ideal BA, for patients and physicians, should allow pain relief and an improvement of the functional capacity, with a low risk of adverse events, a long time prior to perceiving the need for a new dose and self-administration at home, when possible. **CONCLUSIONS:** Although efficacy and safety are key for patients with rheumatic diseases and rheumatologists to make a choice over a BA, the need for a low frequency of administration and the administration method also play an important role as preference attributes for BAs in Spain.

PSY88

PREFERENCES OF SPANISH PATIENTS OVER THE ATTRIBUTES OF BIOLOGICAL AGENTS FOR THE TREATMENT OF RHEUMATIC DISEASES DEPENDING ON THE ADMINISTRATION ROUTE

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OBJECTIVES: Biological agents (BA) to treat rheumatic diseases are commonly administered by either the subcutaneous or the intravenous route. The objective of this study was to assess rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PA) Spanish patients' preferences over BA considering the administration route. **METHODS:** Observational, cross-sectional design. Participants were RA, AS and PA patients (diagnosed ≥2 years prior to study entry; currently or previously (≤1 year ago) receiving BA for a minimum of 1 year. Conjoint analysis was performed to define preferences over 8 scenarios combining 4 attributes ['Administration method' (ADMINISTRATION), 'Pain relief and improvement of the functional capacity' (RELIEF), 'Risk of adverse events' (AE) and 'Time until perceiving the need for a new dose' related to the frequency of administration (TIME)]. Relative importance (RI) was calculated for patients on subcutaneous or intravenous administration, respectively. **RESULTS:** A total of 488 patients [male=50.9%; mean (SD) age=50.6 (12.06) years; RA=33.8%, AS=32.4%, PA=33.8%; mean time from diagnosis=12.6 (8.2) years; receiving currently BA=98.2%] were included. The patients currently receiving subcutaneous (n=305) or intravenous (n=174) administration with BA gave highest importance to 'RELIEF' (45.4% and 46.7%) and 'AE' (28.2% and 31.8%), followed by 'ADMINISTRATION' (19.7% and 10.2%) and 'TIME' (6.7% and 11.3%, respectively). Both groups of patients preferred to stay on the same route of administration, either subcutaneous or intravenous, they had been on. Moreover all patients considered most crucial a longer time until perceiving the need for a new dose (8 over 4 over 2 over 1 week). **CONCLUSIONS:** Spanish patients with rheumatic diseases placed high importance on pain relief and risk of AEs as preference attributes for BAs. The frequency of administration (time until perceiving the need for a new dose) also plays a crucial role as all patients indicated their preference for lower vs. higher frequencies of BA administration.

PSY89

PREFERENCE FOR RITUXIMAB SUBCUTANEOUS (SC) AND INTRAVENOUS (IV) AMONG PATIENTS WITH CD20+ NON-HODGKIN'S LYMPHOMA (NHL) COMPLETING THE RASQ MEASURE IN RANDOMIZED PHASE III STUDIES PREFMAB AND MABCUTE

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OBJECTIVES: Rituximab SC reduces administration times (~5 minutes) compared with the IV route (~4 hours). We examined the extent of patient preference for rituximab SC versus IV in the PrefMab and MabCute studies using the Rituximab Administration Satisfaction Questionnaire (RASQ). **METHODS:** In PrefMab (NCT01724021) patients with untreated CD20+ DLBCL/FL received 1 cycle of IV rituximab (375mg/m^2) followed by either SC rituximab (1400mg, x3) then IV rituximab (x4), or IV rituximab (x3) then SC rituximab (x4), with chemotherapy. In MabCute (NCT01461928) patients with relapsed/refractory CD20+ indolent NHL received induction rituximab IV (375mg/m^2; 1 cycle) then rituximab SC (1400mg; cycles 2–8) plus 6–8 chemotherapy cycles. RASQ evaluated preference by assessing patients' perceptions of the impact of administration route and treatment satisfaction. Conceptual validation of RASQ has been conducted and psychometric data will be reported. **RESULTS:** Median RASQ scores for PrefMab were: convenience IV (n=211) 58.3 (interquartile range: 41.7–75.0) and SC (n=207) 83.3 (75.0–91.7); satisfaction: IV (n=211) 75.0 (62.5–87.5), SC (n=208) 87.5 (75.0–100.0); impact on daily life: IV (n=145) 50.0 (41.7–83.3), SC (n=163) 83.3 (83.3–100.0); physical impact IV (n=211) 83.3 (66.7–100.0), SC (n=208) 83.3 (75.0–100.0); psychological impact IV (n=211) 80.0 (65.0–90.0), SC (n=208) 88.8 (75.0–95.0). SC administration was preferred by 80.3% and 85.9% of patients with IV or SC as most recent dose, respectively. Results were similar irrespective of treatment sequence. Median RASQ scores for MabCute (n=92) were: convenience: IV 58.3 (33.3–66.7), SC 83.3 (66.7–83.3); satisfaction: IV 62.5 (50.0–87.5), SC 87.5 (75.0–100.0); impact on daily life: IV 58.3 (41.7–66.7), SC 83.3 (66.7–83.3); physical impact IV 75.0 (66.7–91.7), SC 83.3 (66.7–91.7); psychological impact IV 70.0 (60.0–85.0), SC 85.0 (75.0–95.0). **CONCLUSIONS:** Consistent patient satisfaction and preference for SC versus IV rituximab was demonstrated in the PrefMab and MabCute studies. RASQ is a reliable and valid measure of patient treatment preference.

PSY90

A SYSTEMATIC LITERATURE REVIEW OF THE HUMANISTIC BURDEN OF MULTIPLE MYELOMA

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OBJECTIVES: We conducted a systematic literature review to identify published evidence from observational studies on the humanistic burden of multiple myeloma (MM). **METHODS:** We searched MEDLINE, Embase, EconLit, and the Cochrane Library for English-language articles and analysed these qualitatively. **RESULTS:** The review identified 20 publications based on 18 observational studies; these were mainly cross-sectional in design (n=14). Most studies (n=15) examined populations with MM in general, typically without stating the proportion with relapsed (R) or relapsed and refractory (RR) MM. Fewer studies examined patients with newly-diagnosed MM (n=2) or RMM/RRMM (n=1). Health-related quality of life (HRQoL) was typically assessed using validated cancer-specific instruments (e. g., the EORTC-QLQ-C30: n=9; and the MM-specific EORTC-QLQ-MY20: n=4). On average, patients with MM had poorer HRQoL compared to the general population (n=6), and compared to patients with certain other hematologic cancers (n=2). MM patients whose disease duration ranged from diagnosis to 11 years had greater physical function impairment ($p<0.001$) than other hematologic cancer patients. Other complaints included fatigue, bone pain, tingling, and non-specific pain. Patients on active treatment had worse side effects than those in a first treatment-free interval ($p<0.001$); the latter had better scores on HRQoL dimensions including role and social function, future perspectives, and body image (all $p<0.05$). Between baseline and one year, patients experienced worsening on the EORTC-QLQ-C30 global health scale ($p<0.001$) and in fatigue, nausea/vomiting, and pain scores (all $p<0.05$). Symptomatic patients had lower physical functioning scores ($p<0.05$) than asymptomatic patients; those with severe symptoms had lower EORTC-QLQ-C30 global health scores ($p<0.05$; mild/moderate symptoms: p=NS). Fatigue, bone pain, and anaemia were associated with lower. **CONCLUSIONS:** HRQoL in patients with MM deteriorates with disease duration, symptom severity, disease progression, or development of complications. This evidence suggests substantial unmet needs in MM patients.

PSY91

PATIENT-REPORTED OUTCOMES IN MODERATE TO SEVERE HEMOPHILIA PATIENTS: FINDING FROM A CROSS-SECTIONALSTUDY IN KOREA

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OBJECTIVES: There are approximately 2,000 hemophilia patients in Korea, but patient-reported outcome (PRO) studies involving a large number of hemophilia patients have been rarely studied. The aim of this study was to assess PROs in moderate to severe hemophilia patients in Korea. **METHODS:** It was a cross-sectional, multi-centered and observational study. Moderate to severe, male hemophilia patients aged 8 to 65 were recruited at 2 of Korea Hemophilia Foundations and 3 other pediatrics from November 2012 to September 2013. All patients completed self-reported questionnaires to measure patients' characteristics and PROs including health-related quality of life (HRQoL) and productivity loss. HRQoL was examined using EQ-5D, ranged 0-1, which higher values indicate better HRQoL and Heamo-QoL, ranged 0-100, where higher values imply lower HRQoL. Productivity loss was estimated with absenteeism and presentism in terms of lost productivity time (LPT). **RESULTS:** For a total of 605 patients (mean age, 29.3 years; 88.6% with severe hemophilia) enrolled in this study, the mean scores of heamo-QoL and EQ-5D were 32.28 and 0.68 respectively. The mean scores of EQ-5D in this study are comparable to 0.68 in rheumatoid arthritis patients from Korea Observational Study Network for Arthritis. Significantly lower EQ-5D was found in patients with the following clinical factors compared to those with reverse conditions; joint bleedings (0.68 vs. 0.73, $p=.001$),